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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,533	LAL ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-29,31,32 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29,31,32 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 10/8/03
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/22/05
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Claims 21-44 are pending in this application and claims 21-29, 31, 32 and 36-38 are the subject of this Office Action. The Examiner apologizes for mistakenly stating these claims were withdrawn. However, on the latest version of the claims, it appears that some of these claims are "amended – withdrawn." Clarification is requested.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Rejoinder Request

A. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. Specification

A. The objection to the specification has been withdrawn in view of Applicants' amending the first line of the specification to claim priority to PCT/US99/14484.

B. The Bibliographic Data Sheet will be updated upon allowance to claim benefit to U.S. Provisional Applications 60/094,983, filed 7/31/98; 60/102,686, filed 10/1/98 and 60/112,129, filed 12/11/98.

4. Claim Objections

A. All claim objections have been withdrawn in view of Applicants amending the claims to recite "the" instead of "a" where appropriate.

5. Claim Rejections - 35 USC § 101

A. Claims 21-29, 31, 32 and 36-38 remain rejected under 35 USC 101 for the reasons already of record on pages 3-4 of the Office Action dated 6/30/03. Applicants argue that the claimed polypeptides are identified as human signal peptide-containing proteins, abbreviated as HSPP. As such, the claimed invention has numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease, none of which require knowledge of how the polypeptide actually functions. Applicants also argue that there is, in addition, direct proof of the utility of the claimed invention and that Applicants submit with this paper the Declarations of Bedilion and Furness describing some of the practical uses of the claimed invention in gene and protein expression monitoring applications as they would have been understood at the time of the patent application.

The Bedilion Declaration states that "persons skilled in the art would appreciate that CDNA microarrays that contained the SEQ ID No:120-encoding polynucleotides would be a more useful tool than cDNA microarrays that did not contain the polynucleotides in connection with conducting gene expression monitoring studies on proposed (or actual) drugs for treating cancer, inflammation, and developmental disorders for such purposes as evaluating their efficacy and toxicity." The Furness Declaration states that "the claimed polypeptide can be used in protein expression analysis techniques such as 2-D PAGE gels and western blots. Using the claimed invention with these techniques, persons of ordinary skill in the art can better assess, for example, the potential toxic affect of a drug candidate." Therefore, the claimed invention has specific, substantial, real-world utility by virtue of its use in

toxicology testing, drug development and disease diagnosis through gene expression profiling. Applicants also argue that the law never requires the knowledge of the biological role of a protein to establish utility.

These arguments have been considered, but are not deemed persuasive. The asserted utility in gene expression monitoring assays is thus not substantial, because significant further research would have to be conducted to determine which diseases correlate with altered forms or levels of the claimed polynucleotides, and whether the claimed polynucleotides are overexpressed or underexpressed in the diseased tissue. Furthermore, since any expressed polynucleotide can be added to a microarray for gene expression monitoring, the asserted utility is not specific to the claimed polynucleotides. The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a credible, specific and substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696.

While the examiner agrees that any polynucleotide, including the claimed polynucleotides, can be used in a cDNA microarray, such does not confer patentable utility on the claimed polynucleotides. Since any polynucleotide can be used in a microarray, such a use is not specific to the claimed polynucleotides. Just as any orphan receptor can be used in an assay to screen for ligands, such does not confer patentable utility on a particular orphan receptor. Such can be done with any orphan receptor, and thus the asserted utility is not specific. Furthermore, since the specification does not disclose a correlation between any disease or disorder and an altered level or form of the claimed polynucleotides, the results of gene expression monitoring assays would be meaningless without significant further research. Therefore, the asserted utility is also not substantial.

Applicant refers to the Bedilion declaration as explaining the many reasons why a person skilled in the art reading the instant application would have understood that application to disclose the claimed polynucleotide to be useful for a number of gene expression monitoring applications, such as a probe for expression of the polynucleotide in connection with the development of drugs and the monitoring of the activity of such drugs. The Bedilion declaration discusses microarrays and Northern analysis for measuring such. Specifically, Applicant quotes from the Bedilion declaration that a person skilled in the art would have been able to use the claimed polynucleotide in gene expression monitoring to develop new drugs for the treatment of cell proliferative and developmental disorders. This is not found to be persuasive. The instant specification does not substantiate a link between the claimed polynucleotides

and any specific cell proliferative or developmental disorder. The specification merely discloses that the claimed polynucleotides are structurally related to growth factors, and that they are expected to be involved in cell proliferative and developmental processes (and thus, disorders). The specification does not disclose the results of the required control in order to draw any conclusions regarding disease, namely, that the claimed polynucleotide is not expressed (or is expressed at an altered level or form) in the corresponding healthy tissues. Many genes expressed in diseased tissues have nothing whatsoever to do with the disease and are not targets for drug development or toxicology. For example, actin and histone genes are expressed in diseased tissues; they are constitutively expressed in all tissues. These are not suitable targets for drug development or toxicology studies, since disruption of these genes would kill the patient.

A conclusion of Dr. Bedilion is that a person skilled in the art at the time of the invention would have concluded that a cDNA microarray containing the claimed polynucleotide would be a more useful tool than a microarray lacking the claimed polynucleotide in connection with conducting gene expression monitoring studies on proposed or actual drugs for treating cell proliferative or developmental disorders for such purposes as evaluating the efficacy and toxicity. Again, this is not found to be persuasive, because the instant specification has not established that the claimed polynucleotides are expressed at altered levels or forms in diseased tissue as compared with the corresponding healthy tissue. If the claimed polynucleotide were in a microarray and a compound caused decreased expression of the claimed polynucleotide, what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate the disease? If it had been disclosed that the claimed polynucleotide is expressed at a higher level in a particular cell proliferative diseased tissue as compared with the corresponding healthy tissue, then the skilled artisan would know that a compound that decreased expression of the polynucleotide is a good potential cell proliferative disease drug. However, that is not disclosed by the instant specification. The claimed polynucleotides may very well be expressed at equivalent levels in healthy tissues. If that is the case, then the compound would not be a good potential drug. The claimed polynucleotides may also very well be expressed at a lower level in a particular cell proliferative diseased tissue as compared to the corresponding healthy tissue. Then a compound that decreased expression of the claimed polynucleotides would *not* be a good potential drug. Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended

that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

The Bedilion declaration also explains how cDNA technology can be used to conduct gene expression monitoring evaluations. Applicant points to Dr. Bedilion's pages of text and numerous subparts explaining the importance of this technology. Appellant points to Dr. Bedilion's explanation that those skilled in the art at the time of the invention without any doubt would have appreciated the criticality of toxicity testing. This is not found to be persuasive. There is no doubt that cDNA microarray technology is an extremely valuable technique in gene expression monitoring, toxicology testing, and drug efficacy testing. However, the claims are not drawn to the technique. The claims are directed to polynucleotides which have not been disclosed as being associated with any particular disease or condition by its being expressed at an altered level or form in diseased tissue as compared to the corresponding healthy tissue. Any such polynucleotide could be added to a microarray. Thus, this asserted utility is not specific. Determining the relationship between the claimed polynucleotides and any specific disease or disorder would require significant further research. Therefore, this asserted utility is also not substantial.

Applicant argues that the Bedilion declaration establishes that persons skilled in the art, guided by the instant specification, at the time of the invention would have wanted their cDNA microarrays to comprise the claimed polynucleotide, because a microarray comprising the claimed polynucleotide would provide more useful results in the kind of gene expression monitoring studies that microarrays lacking the claimed polynucleotide. This is not found to be persuasive. The specification has not linked the claimed polynucleotide with any specific disease state or disorder, as discussed above and in previous Office Actions. Adding the claimed polynucleotide to a microarray would not make the microarray any more valuable than adding any other "orphan" polynucleotide. The asserted utility is not specific to the claimed polynucleotide. Cell proliferative disorders include cancers, psoriasis, warts and slow-closing wounds. Developmental disorders can affect any tissue at any time in its development. Even if it could be assumed that the claimed polynucleotides play a role in a cell proliferative or developmental disorder, determining which disorders are involved and how the claimed polynucleotides are altered during the disorder requires significant further research.

The issue that a biological role is not required to establish a utility of a polynucleotide would, itself, not be a sufficient reason to hold a lack of utility. However, as discussed above, this, along with the

fact that Applicants have not linked this polynucleotide to any specific disease state is sufficient to conclude that the present invention lacks utility.

Applicant urges that it is undisputed that known members of the signal peptide-containing protein family, including HSPP- 120, are useful. Secretory proteins include hormones, cytokines, chemokines, and extracellular matrix molecules. These are the major factors involved in cellular signaling, immune defense, blood coagulation, and cell adhesion. This is not found to be persuasive. This SPP family is functionally highly diverse, as evidenced by Applicants admission on the record. When there is great functional diversity in a structurally related class of compounds, the class cannot be used to predict a utility for a new compound that fits in the class by structural similarity. Such is the case here.

The fact that a recent Blast shows that the SEQ ID NO:120 polypeptide is 99.6% identical to the adenomatosis polyposis coli down-regulated 1 protein (DRAPC1)(see Exhibit A) is not persuasive. Applicants argue that DRAPCI shows increased expression in colon tumors and may be useful as a diagnostic marker for colon cancer (Takahashi et al. (2002) Cancer Res. 62:5651-5656). This corroborates the statement on page 54 of the Specification that the SEQ ID NO:120 polypeptide and the polynucleotides encoding it may be useful in the diagnosis and treatment of cancer. However, this utility, or homology to DRAPCI was not disclosed in the specification as originally filed.

Applicant further argues that the rejection is incorrectly based on the grounds that the use of an invention as a tool for research is not a substantial use. Appellant urges that only a limited subset of research uses are not substantial: those in which the only known use for the claimed invention is to be an object of further study, thus merely inviting further research. This is not found to be persuasive. As discussed above, whereas a scale or a microarray or a gas chromatograph has patentable utility as a research tool, the objects being evaluated with those research tools do not necessarily have patentable utility. In the instant case, the claimed polynucleotide is not disclosed as having a specific activity, or having any property (such as a differential pattern of expression in diseased tissue) that can be specifically useful. The claimed invention is, in fact, the object of further study, merely inviting further research. None of the utilities asserted for the claimed polynucleotide meets the three-pronged test of being specific, substantial and credible.

Applicant challenges the legality of the Patent Examination Utility Guidelines. Since an Examiner has no authority to comment on the legality of the Guidelines, this issue will be reserved for ruling by the Board of Patent Appeals and Interferences. It is believed that all pertinent arguments have been addressed.

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 21-29, 31, 32 and 36-38 remain rejected under 35 USC 112 for the reasons already of record on page 4 of the Office Action dated 6/30/03 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Claims 21-29, 31, 32 and 36-38 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-6 of the Office Action dated 6/30/03. Applicants argue that the disclosure enables the claimed invention. Claims 21 and 31, for example, recite that the claimed polypeptides and polynucleotides comprise "naturally occurring" sequences and through the process of natural selection, nature will have determined the appropriate sequences. Given the information provided by SEQ ID NO:254, one of skill in the art would be able to routinely obtain "a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:254," and fragments thereof.

These arguments have been considered, but are not deemed persuasive for the reasons already of record in the Office Action dated 6/30/03. Though the claims recite "naturally occurring," the breadth of the claims is still excessive. Again, polynucleotides which are 90% identical to, or comprise at least 60 contiguous bases SEQ ID NO:254 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotide. Similarly, polypeptides which are at least 90% identical to, or are fragments of, SEQ ID NO:120 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:120.

Again, Applicants provide no guidance or working examples of polypeptides or polynucleotides which are of any length other than that of the full-length of SEQ ID NO:120 or 254, including molecules which are at least 90% identical to SEQ ID NO:120 or 254, or fragments thereof, nor do they provide a *function* of these nucleic acid molecules, or of the proteins and fragments which they encode. Furthermore, it is not predictable to one of ordinary skill in the art what the functions of these polynucleotides, or polypeptides are. Finally, it is not predictable to the artisan how to make a functional polypeptide or polynucleotide which is less than the full-length of SEQ ID NO:120 or 254 since it is not predictable which residues or nucleic acids are critical for function of the molecule.

Furthermore, Applicants provide no guidance or working examples of diseases linked with any and all HSPPs, or how to treat any diseases, nor would it be predictable to the artisan what diseases could be treated by the claimed invention, or how to make and use the claimed pharmaceutical compositions.

Therefore, the breadth of the claims is excessive with regard to Applicants claiming all polypeptide and polynucleotides which are less than the full-length of SEQ ID NO:120 or 254, including those which are at least 90% identical to these molecules as well as immunogenic fragments thereof. There is also a lack of guidance and working examples of these polypeptides, polynucleotides and pharmaceutical compositions. Applicants do not provide a function of these polypeptides or polynucleotides which are other than the full-length molecules, nor do they provide any guidance as to which residues or nucleic acids are required to maintain function of these molecules. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make and use a functional polypeptide or polynucleotide other than the full-length molecules, or for what diseases to treat using the claimed compounds, leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 21-29, 31, 32 and 36-38 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of the Office Action dated 6/30/03. Applicants argue that structural features of SEQ ID NO: 120 are described, for example, in Table 2 and, given SEQ ID NO:120 and SEQ ID NO:254, one of ordinary skill in the art would recognize naturally-occurring variants of SEQ ID NO: 120 having 90% sequence identity to SEQ ID NO:120 and naturally-occurring variants of SEQ ITD N0:254 having 90% sequence identity to SEQ ID NO:254. Accordingly, the Specification provides an adequate written description of the recited polynucleotide and polypeptide sequences.

Applicants bring to the Examiner's attention Brenner et al. ("Assessing sequence comparison methods with reliable structurally identified distant evolutionary relationships," Proc. Natl. Acad. Sci. USA (1998) 95:6073-6078). Through exhaustive analysis of a data set of proteins with known structural and functional relationships and with <90% overall sequence identity, Brenner et a1. have determined that 30% identity is a reliable threshold for establishing evolutionary homology between two sequences aligned over at least 150 residues and that the written description inquiry in certain cases was based on the state of the art at essentially at the "dark ages" of recombinant DNA technology.

These arguments have been considered, but are not deemed persuasive. Regardless of whether or not the claims are drawn to "naturally occurring" variants, or that the present technology is more advanced than the "dark ages," the specification provides a written description of only one nucleic acid constructs (SEQ ID NO:120). No other species are described, or structurally contemplated, within the

instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of HSPP proteins claimed, or fragments thereof, because it is unknown and not described what structurally constitutes any different nucleic acids encoding these proteins, or nucleic acids encoding these proteins from any different species, which are further not described, or any different nucleic acid sequence that is "at least 90% homologous" to that depicted as SEQ ID NO:120/254, or any nucleotide sequence that encompasses unknown and undescribed promoter sequences, introns, allelic variants, or other sequences comprising related nucleic acid sequence fragments; thereby not meeting the written description requirement under 35 USC 112, first paragraph. It is believed that all pertinent arguments have been addressed.

7. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants removal of the terms "biologically active" and "HSPP" from the claims. The Examiner apologizes for including claims 36 and 37 in the rejection of the term "HSPP." Regardless, the point is moot.

8. Claim Rejections - 35 USC § 102

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' amendment to the claims to recite that the immunogenic fragment is greater than 10 amino acids and that the present application has a priority date earlier than Rosen et al. and the publication date of the sequence of Bonaldo et al.

7. Claim Rejections - 35 USC § 103

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' argument that the present application has a priority date earlier than Rosen et al. and the publication date of the sequence of Bonaldo et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 29, 2003

Gary L. Kunz
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